UNITED STATES FOOD & DRUG ADMINISTRATION

Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002: Requirement to Submit Mail Tracking Number for Articles of Food Arriving by International Mail

RIN 0910-AI75 - NEW

SUPPORTING STATEMENT – **Part A: Justification**:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) rulemaking intended to help implement of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). Section 801(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(m)), requires that the Food and Drug Administration (FDA or we) issue regulations requiring the submission of prior notice for food, including food for animals, that is imported or offered for import into the United States. FDA's regulations requiring such notice appear in 21 CFR Part 1; Subpart I *"Prior Notice of Imported Food."*

Advance notice of imported food allows FDA, with the support of the U.S. Customs and Border Protection (CBP), to target import inspections more effectively and help protect the nation's food supply against terrorist acts and other public health emergencies.

We are proposing to amend the regulation to include a requirement that the name of the mail service and a mail tracking number be submitted for articles of food arriving by international mail, in the prior notice of the article of food to FDA. This information will assist FDA's abilities to work with the U.S. Customs and Border Protection (CBP) and the United States Postal Services (USPS) to locate, hold, and inspect mail shipments of articles of food when there is information that the article could pose a threat to the U.S. food supply and will assist FDA in better utilizing its resources efficiently and effectively in ensuring the safety of food articles arriving by international mail.

2. Purpose and Use of the Information Collection

Our regulations require that prior notice of imported food be submitted electronically using CBP's Automated Broker Interface of the Automated Commercial Environment (ABI/ACE) (§1.280(a)(1)) or through the FDA Prior Notice System Interface (PNSI) (§1.280(a)(2)). PNSI is an electronic submission system available on the FDA Industry Systems page at http://www.access.fda.gov/.

For food articles arriving by international mail, the information that must be submitted includes the name of the submitter and transmitter (if different from the submitter); entry type; the identify of the article of food, including complete FDA product code; the manufacturer, for an article of food no longer in its natural state; the grower, if known, for an

article of food that is in its natural state; the FDA Country of Production; the name of any country that has refused entry of the article of food; the shipper; the country from which the article of food is shipped (i.e. mailed); the anticipated date of mailing; and the name and address of the U.S. recipient.

If the food is not arriving by international mail (e.g. it is arriving via private delivery service), the information must include anticipated arrival information, such as anticipated port, date and time of arrival. The rule requires the submission of anticipated arrival information for such shipments to provide FDA with information necessary for planning examinations and communicating with CBP for enforcement and examination purposes. 68 FR 58974, 59009 and 59011 (2003). The rule currently does not require anticipated arrival information for food articles arriving by international mail.

The lack of anticipated arrival information for food articles arriving by international mail results in challenges to FDA's ability to track or locate the movement of such articles. This decreases FDA's ability to prevent food articles from entering the U.S. food supply that present a public health risk or bio-terrorism threat. The additional requirement to provide the tracking number for food articles arriving by international mail will serve similar purposes that anticipated arrival information does for private delivery mail and will better enable FDA to locate and inspect food articles that present a risk to the U.S. food supply.

Description of Respondents: Persons submitting prior notice for articles of food imported or offered for import into the United States by international mail. Any person with knowledge of the required information may submit prior notice for an article of food. Thus, the respondents to this information collection include importers, owners, ultimate consignees, shippers, and carriers with knowledge of the required information about food, including food for animals, that is imported or offered for import into the United States.

3. Use of Improved Information Technology and Burden Reduction

As noted above, FDA regulations require that prior notice of imported food be submitted electronically either through ABI/ACE or the FDA PNSI. Thus, we estimate that one hundred percent (100%) of the respondents will use electronic means to submit the required information.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The information collection poses no undue impact on small entities. We have conducted a preliminary regulatory impact analysis in support of the proposed rulemaking.

6. Consequences of Collecting the Information Less Frequently

The information collection is consistent with statutory and regulatory requirements.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.11, we published a proposed rule in the Federal Register of November 1, 2023 (88 FR 74939) that included an analysis of burden and solicited public comment for the proposed information collection.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted is point of contact name, business address, business phone number, and business e-mail address. We determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, neither the contractor nor FDA uses *name* or any other personal identifier to retrieve records from the information collected. Through appropriate collection methods, we have minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). We will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information. Consistent with 5 CFR 1320.5(d)(2)(vii), data will be kept private to the extent allowed by law

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1. Estimated Annual Reporting Burden

21 CFR Part 1; Information Collection Activity	No. of Respondents	Average No. of Responses per Respondent	Total Annual Responses	Average One-time Burden per Respondent (in minutes)	Average Burden per Response (in minutes)	Total Annual Hours
1.281(b)(10) – information included in prior notice	5,460	143	781,219	30	4	54,811

Based on 2021 fiscal year data from our Online Reporting Analysis Decision Support System, we estimate that 26,200 persons submit prior notice through PNSI. We assume 5,460, or roughly 20%, are importing or offering for import articles of food by international mail. The proposed requirement to submit tracking information only applies to persons importing or offering for import articles of food by international mail. The number of prior notices for international mail entries per respondent per year ranges from 1 to approximately 5,000. The average number of prior notice submissions for international mail entries per person per year is approximately 143. Of the more than 18 million prior notices received by FDA per year, approximately 781,219 are identified as "*mail*."

We estimate a one-time average burden of 30 minutes per respondent to learn the new requirement and coordinate with mail servicers to establish best practices for receiving and providing the information. In addition to the one-time burden, we estimate an average recurring annual burden of 4 minutes per prior notice mail submission. The one-time total burden for all the 5,460 respondents amounts to 163,800 minutes (5,460 x 30). The total recurring burden for all the 781,219 mail entries is 3,124,876 minutes (781,219 x 4). Therefore, we estimate the average total annual recurring burden in hours to be 54, 811 (163,800 + 3,124,876 ÷ 60).

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

We estimate an annual cost of $1,000,000 to operate and maintain the Prior Notice System Interface (PNSI).

15. Explanation for Program Changes or Adjustments

We estimate 781,219 responses and 54,811 hours annually will result from finalization of the proposed rule.

16. Plans for Tabulation and Publication and Project Time Schedule

The information from this collection will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Displaying the OMB approval date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.